REMARKS

The Communication mailed September 22, 2004, has been received and reviewed. Claims 1-23 are pending in the application. Claims 1-22 were subjected to restriction. Applicants provisionally elect, with traverse, to prosecute the claims of Group I, claims 1-16. Upon election of Group I, applicants were further required to elect from the following subinventions: i) one of the viruses identified in claim 13, ii) either the adenovirus early protein from early region 1 or early region 2, and iii) one of the methods of determining the effect of a compound on the viral life cycle. Applicants assert that currently amended claims 3 and 13 moot the requirement to elect a single virus. Amended claims 1, 7, and 12 moot the requirement to elect either adenovirus early protein. Applicants choose to elect from the designated subinvention iii) the following method: (d) examining the virus' activity.

Applicants respectfully traverse this restriction and submit that the Groups identified as Groups I-III in the Office Action should be joined and examined as a single group, which applicants elect. As such, applicants request reconsideration of the restriction requirement.

Applicants have amended claims 1, 3, 7, 12, 13 and 17. Claim 23 is new. Examination of the application claims is respectfully requested.

Restriction Requirement

Requirement for restriction is proper under 35 U.S.C. 121, if two or more independent and distinct inventions are claimed in a single application. Further, as set forth in MPEP §803, a patent application may be properly restricted to one of two or more claimed inventions only if the inventions (1) are able to support separate patents; (2) they are either independent or distinct; and (3) the examination and search of independent or distinct inventions can only be made under a serious burden. Applicants respectfully submit that the claims directed to the invention of the groups identified as Groups I-III in the Communication are not drawn to independent or distinct inventions and do not require a burdensome search.

The present invention relates to a method of determining whether a compound influences the life cycle of a virus. More particularly, the invention relates to a method of using cell lines that fully support the complete life cycle of pathogenic viruses and that provide methods for

screening libraries of antiviral compounds for identification of molecules with antiviral activity that can interfere with the life cycle of a pathogenic virus. (Specification, paragraph [008]) As described in the Specification, viral infections may be controlled by antiviral agents that either attack the viral particle directly or that otherwise disrupt the life cycle of the virus by preventing infection, propagation, replication, packaging and/or growth of the virus. (Specification, paragraphs [003] and [004]). The life cycle of the virus may also be disrupted by the absence of a critical compound, whether it is cellular or viral.

In order to examine the effects of the presence or absence of a candidate compound on the life-cycle of a virus, it is preferred to have cell lines that are continuous and that support the life-cycle of the studied virus. After infection of the appropriate cell line with the studied virus and exposure to the candidate compound, it is necessary to assay the possible interactions of the compound with the cell and with the virus. Depending on the virus and the cell line, different methods of assaying the effect of the candidate compound may be used. As such, the requirement to select the presence or absence of a compound, a single virus to study, a particular cell line, and a single interaction assay treats the claimed method of antiviral identification as if it were many hundreds of different individual methods depending on the presence/absence of the compound, type of virus, cell line, and interaction assay.

Restriction between Groups I-III is Improper

MPEP § 806.03 states that when the claims of an application define the same essential characteristics of a single disclosed embodiment of an invention, restriction therebetween should never be required. The claims in Groups I (claims 1-16) and II (claims 17, 21, and 22) are different definitions of the same disclosed subject matter. Group I is drawn to a method for determining whether a compound has antiviral activity. The currently amended Group II claims are dependent from claim 1 and are drawn to a method of determining if a compound has antiviral activity against a first virus, and if a second compound has antiviral activity against a second virus. The claims of Group I vary from the claims in Group II only in breadth and scope of definition and define the same essential characteristics of an enclosed embodiment. As such, restriction between the two groups would appear improper.

Furthermore, the claims in Groups I and Groups III (claims 18-20) define the same

essential characteristics of the disclosed method of identifying antiviral compounds. For a method of identifying antiviral compounds, the method would look for the antiviral effect of both the presence and absence of compounds. As such, the claims of Group I and Group III vary only in breadth and scope of the definition of the same disclosed subject matter, *i.e.,* a method of identifying antiviral compounds.

In reference to the requirement of iii) to elect one of the possible methods of determining the effect of a compound on the viral life cycle (Office Action, page 2 and 3), the claims directed to those methods are merely examples of how the effects of a compound may be monitored. The claims are included to further define characteristics of the invention. Each virus or cell line may require the use of different methods which can be determined by one of skill in the art. Moreover, a given compound may have multiple effects on the viral life cycle requiring more than a single method to monitor those effects. As such, a person skilled in the art may determine, for a specific kind of virus, which methods are available in the art, and which methods could be used. Therefore, a requirement to elect a single method of determining the effect of a compound would appear to be improper.

The Groups are not Distinct

According to the MPEP § 802.01, inventions are "distinct" if two or more subjects as disclosed in the specification are related, but are capable of separate manufacture, use, or sale as claimed, and are patentable (novel and unobvious) over each other. If the inventions are not distinct, restriction is never proper (MPEP § 808.02).

The claims of Groups I and II define differently the same disclosed subject matter and are not capable of separate use. Group I is drawn to a method for determining whether a compound influences a phase in the life cycle of a virus and Group II is drawn to a method of determining if a first compound influences a phase in the life cycle of a first virus and if a second compound inhibits a phase in the life cycle of a virus. The use of amended Group II as claimed is essentially the same as using a first Group I and a second Group I side by side. More particularly, the use of Group II is the use of Group I for a first cell, a first virus, and first compound used in parallel with a second Group I for a second cell, a second virus, and a second compound. As such, the use of Group II as claimed is also using Group I and cannot be used separately from Group I.

Groups I and III are not distinct or independent in that they are related in their operation, function, and effect. The methods of antiviral identification of both groups operate by setting up a cell culture system capable of supporting a virus life cycle and then perturbing the system and observing the effect on the life cycle of the virus. Similarly, the designated Groups I and III have related function in that they identify antiviral compounds by looking for changes in viral growth after manipulating the virus culture system. Groups I and III also have the related effect of pointing to compounds that have antiviral capabilities. As such, Groups I and III are not distinct and restriction therebetween is improper.

Additionally, according to MPEP § 808.02, even if the related claims are distinct, the Examiner, in order to require restriction, has the burden of showing one or more of the following: (1) separate classification, (2) a separate status in the art when they are classified together, and (3) a different field of search. As such, if the claimed multiple inventions belong to the same classification, are in the same field of search, and there is no indication of a future change in classification and field of search, restriction is improper. The following discussion demonstrates that the claims of the groups identified as Groups I-III in the Communication are not separately classified, do not have a separate status in the art, are in the same field of search and, therefore, that the restriction requirement is improper.

1. The Claims of the Groups identified as Groups I-III in the Communication are Not Separately Classified

MPEP § 808.02(A) explains that a separate classification means that each distinct invention has attained recognition in the art as a separate subject for inventive effort, and also belongs to a separate field of search. The specification of the instant application states "[t]he invention relates to the field of identification of antiviral compounds." (Specification, paragraph [002]). Each of the designated Groups I-III is a member of the same classification and the same subject of inventive efforts, *i.e.* the identification of antiviral compounds. Moreover, the Office Action stipulates that all three Groups are classified in class 435, subclass 5. (Office Action, page 2). As such, the designated Groups I-III are not separately classified.

2. The Claims of the Groups identified as Groups I-III in the Communication Do Not Have a Separate Status in the Art When They are Classified Together

As explained in MPEP § 808.02 (B), even though the inventions may be classified together, each subject can be shown to have formed a separate subject for inventive effort when an explanation indicates a recognition of separate inventive effort by inventors. The MPEP further explains that separate status may be shown by citing patents as evidence of such status and of a separate field of search. In the present case, the Examiner makes no such showing. Further, the specification for the instant application gives no indication that separate inventive efforts were made by the inventors, or that separate inventive efforts were necessary for the claimed methods. Accordingly, the claims of the Groups identified as Groups I-III should not be deemed to have separate status in the art.

3. The Claims of the Groups identified as Groups I-III in the Communication Do Not Have Different Fields of Search

MPEP § 808.02(C) explains that where it is necessary to search for a distinct subject in places where no pertinent art to the other subjects exists, restriction between distinct inventions may be proper. The Office Action, on page 5, number 7, asserts that a search for any one of the groups would not be co-extensive with the search required to examine the others. However, the claims of Groups I-III are all directed to methods of identifying antiviral compounds. Consequently, a search for a Group I method of identifying antiviral compounds would be co-extensive with the search for a related and similar Group II or Group III method of identifying antiviral compounds. Therefore, a search for highly related methods of identifying antiviral compounds should not be considered an undue burden on the Patent Office.

Moreover, this application is a continuation of PCT International Patent Application No. PCT/NL02/00296, for which was performed a PCT international search report, dated October 7, 2002. As such, the search burden on the Patent Office may be substantially decreased.

Therefore, the claims of the instant application do not disclose distinct inventions. The Examiner has failed to show: (1) separate classification, (2) a separate status in the art when they are classified together, and (3) a different field of search. As such, restriction would appear improper.

Election of Species

The amendments to claims 3 and 13 remove the necessity to respond to this requirement for election of species.

CONCLUSION

Because the alleged multiple inventions of Groups I-III do not satisfy the requirements for a proper restriction, Applicants respectfully request the restriction requirement be reconsidered and removed with respect to the Groups identified as Groups I-III, and the claims be examined on the merits. Should the Office determine that additional issues remain please contact Applicants' undersigned agent.

Respectfully submitted,

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